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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,509	05/18/2005	Aleardo Koverech	2818-240	7229

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,509	KOVERECH ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejection – 35 USC 112, 1ST paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 –18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment for disorders caused by andropause, does not reasonably provide enablement for the prevention of such disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), " There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands , set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, 1ST paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;

7. The quantity of experimentation needed; and
8. The level of the skill in the art.

The nature of the invention

The invention is in the field of treatment for male sexual dysfunction

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is high, however predictability in terms of prevention of disorders of sexual dysfunction caused by the andropause.

Carnitine has shown promise for improving male sexual function. One double-blind, placebo-controlled study of 120 subjects compared a combination of propionyl-L-carnitine (2 g per day) and acetyl-L-carnitine (2 g per day) against testosterone for the treatment of male aging symptoms (sexual dysfunction, depression, and fatigue).[81] The results indicated that both testosterone and carnitine improved erectile function, mood, and fatigue, as compared to placebo. However, no improvements were seen in the placebo group. This is an unusual occurrence in studies of erectile dysfunction, and it casts some doubt on the study results. (iHerb.com, Carnitine, copyright 1997, printed pages 1-13, especially page 5).

The amount of direction or guidance present

The amount of direction or guidance present is absent in regard to an explanation and/or description as to how a combination of propionyl L-carnitine and acetyl L-carnitine

The presence or absence of working examples

The qualitative presence of working examples within instant specification is lacking. The specification fails to contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention. The instant invention is directed to a method of prevention; however, there is nothing in the instant specification, which suggests prevention of andropause. Working examples of instant specification lack any specification toward any administrative method directed toward treatment and/or prevention. Treatment for andropause is enabled via prior art. In the instant specification, however, there are no adequate examples directed toward administration for said treatment.

The breadth of the claims, quantity of experimentation, and level of skill in the art

The breadth of the claims, due to "preventive" terminology contain metes and bounds that are not adequately suggested, explained or described in instant specification. The quantity of experimentation to one of ordinary skill in the pertinent art is recognized as extensive and routine.

Claim Rejection-35 USC – 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over iHerb.com, Carnitine, copyright 1997, printed pages 1-13, especially page 5).

The referenced article iHerb.com teach:

Carnitine has shown promise for improving male sexual function. One double-blind, placebo-controlled study of 120 subjects compared a combination of propionyl-L-carnitine (2 g per day) and acetyl-L-carnitine (2 g per day) against testosterone for the treatment of male aging symptoms (sexual dysfunction, depression, and fatigue).[81] The results indicated that both testosterone and carnitine improved erectile function, mood, and fatigue, as compared to placebo. However, no improvements were seen in the placebo group. This is an unusual occurrence in studies of erectile dysfunction, and it casts some doubt on the study results.

A double-blind study of 40 men evaluated propionyl-L-carnitine (2 g per day) in diabetic men with erectile dysfunction who had not responded well to Viagra.[82] The results indicated that carnitine significantly enhanced the effectiveness of Viagra.

In another double-blind study, a combination of the propionyl and acetyl forms of carnitine enhanced the effectiveness of Viagra in men who suffered from erectile dysfunction caused by prostate surgery.[99]

The referenced article iHerbs.com teach dosage embodiments at 2g each of propionyl - L - carnitine and acetyl - L - carnitine per day, which are encompassed by instant claims 15 and 16.

The referenced article iHerbs.com do not teach the claim limitations of instant claim 14, which is, use according to claim 1, in which the disorders of the andropause are selected from the group consisting of: reduced libido or sexual drive and reduced quality of erections, including nocturnal erections, depression of mood, reduction of intellectual activity and of spatial orientation capacity, fatigue, irritability, reduced lean body mass, reduced muscular functional capacity, reduced mental concentration, reduced functioning of the hair-growing apparatus, increased visceral fat, atrophy of the skin, and reduced bone density resulting in osteopenia and osteoporosis.

However, one of ordinary skill in the pertinent art of biopharmaceutics and pharmacology would instantly recognize at the time of invention the necessity of

incorporating together the methods and agents as disclosed in instant claims 10-18 with the claim limitations of instant claim 14. One of ordinary skill in the said pertinent art understands that certain pharmaceutical salts and derivatives increase therapeutic bioavailability.

Thus, the referenced article iHerbs.com is prima facie coupled with the conventional practice of one of pertinent skill in the art (to incorporate together with pharmaceutical salts and derivatives thereof to improve absorption/ bioavailability obvious over the central issue of instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H Marschel 5/27/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB